

Environmental Protection Agency

§ 158.2084

assay conditions for small colony expression or detection;

ii. Chinese hamster ovary (CHO) or Chinese hamster lung fibroblast (V79) cells, hypoxanthine-guanine phosphoribosyl transferase (hgp_{rt}) gene locus, accompanied by an appropriate *in vivo* test for clastogenicity; or

iii. CHO cells strains AS52, xanthine-guanine phosphoribosyl transferase (xp_{rt}) gene locus.

§ 158.2084 Experimental use permit biochemical pesticides nontarget organisms and environmental fate data requirements table.

(a) *General.* (1) Sections 158.100 through 158.130 describe how to use this table to determine the terrestrial and aquatic nontarget organisms and fate data requirements for a particular biochemical pesticide product. Notes that apply to an individual test including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section. In general, for all outdoor end-use products including turf, the following studies are required: one avian acute oral, one avian dietary, one acute freshwater fish, and one acute freshwater invertebrate study.

(2) The data in this section are not required for arthropod pheromones when applied at up to a maximum use rate of 150 grams active ingredient/acre/year except when the product is expected to be available to avian species (*i.e.*, granular formulation).

(b) *Use patterns.* The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood/nonfeed crop. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. The indoor use pattern includes products classified under the general use patterns of indoor food and nonfood use. The remaining terrestrial uses include forestry and residential outdoor use. Data are also required for the general use patterns of aquatic food and nonfood crop use.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; Residue of concern=the active ingredient and its metabolites, degradates, and impurities of toxicological concern; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table.* The following table shows the data requirements for experimental use permit biochemical pesticides nontarget organisms and environmental fate. The test notes are shown in paragraph (e) of this section.

TABLE—EUP BIOCHEMICAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns					Test Substance	Test Notes
		Terrestrial	Aquatic	Greenhouse	Forestry, Residential Outdoor	Indoor		
		Food/Feed/Nonfood	Food/Nonfood	Food/Nonfood		Food/Nonfood		
Tier I								
Avian Testing								
850.2100	Avian acute oral toxicity	R	R	NR	R	NR	TGAI, EP	1, 2, 3
850.2200	Avian dietary toxicity	R	R	NR	R	NR	TGAI, EP	1, 2, 3
Aquatic Organism Testing								
850.1075	Fish acute toxicity, freshwater	R	R	NR	R	NR	TGAI, EP	2, 3, 4

TABLE—EUP BIOCHEMICAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Patterns					Test Substance	Test Notes
		Terrestrial	Aquatic	Greenhouse	For- estry, Resi- dential Out- door	Indoor		
		Food/ Feed/ Nonfood	Food/ Nonfood	Food/ Nonfood		Food/ Nonfood		
850.1010	Aquatic invertebrate acute toxicity, freshwater	R	R	NR	R	NR	TGAI, EP	2, 4

(e) *Test notes.* The following test notes are applicable to the data requirements for experimental use permit biochemical pesticides nontarget organisms and environmental fate as referenced in the last column of the table contained in paragraph (d) of this section.

1. Required for the EP when any end-use formulation may contain other ingredients that may be toxic to nontarget organisms or to support arthropod pheromones that would be available to avian wildlife, (e.g., a granular product).
2. Not required for any use groups if the pesticide is highly volatile (estimated volatility $>5 \times 10^{-5}$ atm m³/mol).
3. Preferred test species are: upland game, waterfowl, or passerine for avian acute oral toxicity studies; upland game or waterfowl for avian dietary studies; and coldwater fish for acute freshwater fish studies.
4. Required for the EP when the end-use formulation may contain other ingredients that may be toxic to nontarget organisms.

Subpart V—Microbial Pesticides

SOURCE: 72 FR 61002, Oct. 26, 2007, unless otherwise noted.

§ 158.2100 Microbial pesticides definition and applicability.

(a) This subpart applies to all living or dead microbial pesticides as described in paragraphs (b) and (c) of this section.

(b) *Definition.* *Microbial pesticide* is a microbial agent intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, that:

(1) Is a eucaryotic microorganism including, but not limited to, protozoa, algae, and fungi;

(2) Is a procaryotic microorganism, including, but not limited to, Eubacteria and Archaeobacteria; or

(3) Is a parasitically replicating microscopic element, including, but not limited to, viruses.

(c) *Applicability.* (1) This subpart applies to microbial pesticides as specified in paragraphs (c)(2), (c)(3), and (c)(4) of this section.

(2) Each new isolate of a microbial pesticide is a new active ingredient and must be registered independently of any similarly designated and already registered microbial pesticide active ingredient. Each new isolate for which registration is sought must have a unique identifier following the taxonomic name of the microorganism, and the registration application must be supported by data required in this subpart. This does not preclude the possibility of using data from another isolate, provided sufficient similarity is established, to support registration.

(3) Genetically modified microbial pesticides may be subject to additional data or information requirements on a case-by-case basis depending on the particular microbial agent and/or its parental strains, the proposed pesticide use pattern, and the manner and extent to which the organism has been genetically modified.

(4) Pest control organisms such as insect predators, nematodes, and macroscopic parasites are exempt from the requirements of FIFRA as authorized by section 25(b) of FIFRA and specified in § 152.20 (a) of this chapter.

[72 FR 61002, Oct. 26, 2007, as amended at 77 FR 52612, Aug. 30, 2012]